K024301 MAR 2 4 2003

11. Premarket Notification [510(k)] Summary

Submitted By: LSI SOLUTIONS, Inc.
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Victor, New York 14564
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Contact: Christopher A. Klaczyk, Regulatory Compliance Manager

Common Name: Endoscope and/or accessories

Trade Name: LSI Endoscopic External Accessory Channel and Accessories Product

Classification Name: *Endoscope and accessories* (per 21 CFR §876.1500)

Predicate Device: LSI SOLUTIONS Flexible Suture Placement Device and Accessories Product (K011016)

Description: The LSI Endoscopic External Accessory Channel and Accessories Product is a sterile conduit that can be safely attached to common endoscopes. This Endoscopic External Accessory Channel enables the passage of additional endoscopic instruments to enhance the effectiveness of diagnostic and therapeutic interventions.

Intended Use: The LSI Endoscopic External Accessory Channel and Accessories Product is intended for use as a supplemental conduit that attaches to an endoscope to enable improved access during endoscopic procedures.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 2 4 2003

Mr. Christopher A. Klaczyk
Regulatory Compliance Manager
LSI Solutions, Inc.
7796 Victor-Mendon Road
VICTOR NY 14564 USA

Re: K024301
Trade/Device Name: LSI Endoscope External Accessory Channel Device and Accessories Product
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: II
Product Code: 78 KOG
Dated: December 20, 2002
Received: December 24, 2002

Dear Mr. Klaczyk:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of the letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

7. Statement of Indications For Use

510(k) Number (if known): K024301

Device Name: LSI Endoscopic External Accessory Channel and Accessories Product

Indications For Use:

The LSI Endoscopic External Accessory Channel and Accessories Product is intended for use as a supplemental conduit that attaches to an endoscope to enable improved access during endoscopic procedures.

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K024301

Prescription Use ✓
(Per 21 CFR 801.109)

(Optional Format 3-10-98)